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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,810

01/17/2006

Marc Schwaller

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EXAMINER

MCCORMICK, MELENIE LEE

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

07/10/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<p align="center">Office Action Summary</p>	Application No. 10/527,810	Applicant(s) SCHWALLER, MARC	
	Examiner Melenie McCormick	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 12 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-12 and 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) <input type="checkbox"/> Notice of Informal Patent Application
6) <input type="checkbox"/> Other: _____ |
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DETAILED ACTION

Applicant's amendments with remarks filed 23 April 2007 have been received and considered.

Claim 13 has been cancelled. Claims 23-25 have been added.

Claims 1-9, 11-12 and 14-25 are presented for examination.

Claim Rejections - 35 USC § 112

The previous rejection of claim 16 under 35 U.S.C. 112 second paragraph has been withdrawn in view of Applicants amendment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 12 recite the limitation "Composition according to Claim 10" in line 1. There is insufficient antecedent basis for this limitation in the claims, as claim 10 has been cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 15, and 23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Deckers et al. (US 2002/0106337 A) for reasons set forth in the previous Office Action and discussed below.

Deckers et al. teaches a composition which comprises oil bodies. Deckers et al. also discloses that the composition is useful for topical application to the human body (see e.g. [0002]). Deckers et al. further teach that the oil bodies are derived from plant seeds, including borage and squash (marrow), and that the composition may comprise mixtures thereof (see e.g. [0053]). This reads on a composition comprising borage oil and marrow oil in combination wherein the marrow oil is extracted from the marrow pips and/or the borage oil is extracted from borage seeds, as instantly claimed. As evidenced by encarta.msn.com, pips are seeds (see e.g. encarta.msn.com). Deckers et al. further teach that the composition may additionally comprise seed extract (oil) of soybean (see e.g. [0053]). Please note that the soybean oil extract would inherently contain isoflavones therein. Deckers et al. also disclose that the composition is formulated for topical application for improvement or benefit of the physical appearance, health, fitness or performance of the surface area of the human body (see e.g. [0039]). This reads on a medicinal product, a dermatological agent, a dermocosmetic agent, or a

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nutraceutical agent, as instantly claimed. Please note that although Deckers et al. teach the composition is formulated for topical application, nothing would preclude one from orally administering the composition, as recited in the instantly claimed intended use. This is true because the composition taught by Deckers et al. is essentially an oil body emulsion, which is free from contaminants (see e.g. [0045]). Deckers et al. also teach that the composition may be a toothpaste, which would be suitable for oral administration and reads on a paste as instantly claimed (see e.g. claim 32). Therefore the composition taught by Deckers et al. would be suitable for oral use.

Therefore, the reference is deemed to anticipate the instant claims above.

Applicants argue that Deckers et al. disclose a number of possible plant species which may comprise the emulsion composition taught. Applicants also argue that the Deckers fails to provide any basis for suggestion to one skilled in the art to combine the specific oils instantly claimed from among the various possible combinations disclosed. This is not persuasive, however, as the broad teaching of the reference anticipates the instantly claimed composition. Deckers et al. teaches that borage oil, marrow oil and soybean oil may be present within a composition. Applicants also argue that Deckers et al. do not teach that the composition is formulated for oral administration. This is not persuasive, however, as Deckers et al. teach that the composition may be a toothpaste(see e.g. claim 32). This reads on the instantly claimed composition.

Therefore, the rejection is deemed proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 3, 5-7, 9, 15, 20, 21 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deckers et al. for reasons discussed in the previous Office Action , which are presented and elaborated upon below (US 2002/0106337 A).

Deckers et al. beneficially teach a medicinal product, dermatological, dermocosmetic, or nutraceutical which comprises marrow, borage, and soybean seed oil and is relied upon for the reasons set forth above. Deckers et al. do not explicitly teach that the composition is in the form of an oil or gel.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition comprising borage and marrow seed oil and additionally comprising soybean seed oil, as instantly claimed. One of ordinary skill in the art at the time the claimed invention was made would have been motivated and would have had a reasonable expectation of success in doing so based upon the disclosure of Deckers et al. that such a composition has been prepared and is useful for improvement or benefit of the physical appearance, health, fitness or performance or the surface area of the human body (see e.g. [0039]). The skilled artisan would have been motivated to formulate the composition such that it is suitable for oral administration, as Decker et al. discloses that the composition may be a

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toothpaste (see e.g. claim 32). Because Deckers et al. teach the composition comprises oil bodes (see e.g. abstract), the skilled artisan would be motivated to provide the composition in the form of an oil. In addition, because the composition may be used for a variety of personal care products, the skilled artisan would understand that a gel formulation would be beneficial (see e.g. abstract). This is particularly true of the toothpaste composition, as the skilled artisan would know toothpastes are commonly provided in gel form. The adjustment of particular conventional working conditions (e.g. the result-effective adjustment of particular percentages by weight of the individual components of the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

It does not appear that Applicants have specifically addressed the rejection under 35 U.S.C 103 (a) over Deckers et al. (US 2002/0106337 A).

The rejection is deemed proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11-12, and 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deckers et al. (US 6,146,645), Duranton et al. (US 6,465,421), Francis (US 5,695,748), and Segelman (US 6,017,893) for reasons set forth in the previous Office Action, which are discussed and elaborated upon below.

Deckers et al. (US 6,146,645) beneficially teach a composition for topical application which comprises soybean oil and/or cucurbita (marrow) oil, wherein the oil is obtained from seeds of the plant (see e.g. col 7, lines 35-46). Deckers et al. further teach that the composition is useful for combating hair loss and that the oil extract comprises 1-99% by weight of the composition (see e.g. col 14, lines 10-20). Deckers et al. also teach that the composition may be a food product (food composition or food supplement), a personal care product or a pharmaceutical product (nutraceutical agent) (see e.g. claim 25). Deckers et al. further teach that the composition may be a gum (see e.g. claim 26) or that it may be a cosmetic product, including, among other forms, a skin cream or a facial cream (which read on dermocosmetic/dermatological agent) (see e.g. claim 28).

Duranton et al. beneficially teach a composition which has hair growth-modulating properties (see e.g. col 1, lines 17-18). Duranton et al. further beneficially

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teach that the composition is intended to promote the growth of hair and that the composition contains borage oil (see e.g. claim 1). Duranton et al. also teach that the composition may be administered topically or orally (see e.g. col 6, lines 40-45).

Francis beneficially teaches a mixture (composition) which contains nettle and is used for restoring hair growth (see e.g. claim 1). It is further beneficially taught by Francis that the nettle can be in the form of a powder or a tea (which would be in a form suitable for oral administration) (see e.g. col 3, lines 13-16). Francis further teaches that the mixture is applied to the scalp (topical application) (see e.g. claim 1).

Segelman beneficially teaches a composition for preventing and treating hair loss (see e.g. col 1, lines 11-15). Segelman further beneficially teaches that the composition may be used topically or orally (see e.g. col 1, lines 60-65). It is further disclosed by Segelman that the composition is made from soybeans in powdered form and contains isoflavones (see e.g. col 7, example ii). Segelman also discloses that the topical forms of the composition include ointments, creams, lotions or other solutions, which read on a medicinal product, a dermatological agent, a dermocosmetic agent, or a nutraceutical agent (see e.g. col 6, lines 16-19). It is further disclosed by Segelman that the oral forms of the composition include capsules, tablets and powders (see e.g. col 6, lines 28-56).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit- i.e. treating hair loss/alopecia -since each is well known in the art for the same purpose and for the following reasons. It is well known that it is *prima facie* obvious to combine

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two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose (as well as to use the combination for that purpose). The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. It would further have been obvious to the skilled artisan to provide the composition in the form of a capsule, tablet, granule, paste, gum, oil, wafer capsule, gel capsule, chewing paste, oily jelly or food supplement, as each of the references beneficially teaches that the hair loss compositions comprising the instantly claimed extracts can be used orally or topically. The various forms instantly claimed well known in the art as typical oral or topical formulations, and therefore would have been obvious to one of ordinary skill in the art at the time the claimed invention was made. The adjustment of particular conventional working conditions (e.g. the particular result effective concentration of each component or the particular part of the herb from which each extract is derived) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

With respect to the art rejection above, please note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim (see e.g. claim 14) is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

Applicants argue that Deckers et al. ('645) fails to suggest or disclose the use of borage oil as instantly claimed. Applicants also argue that Duranton ('421), Francis ('748), and Segelman ('893) fail to disclose the marrow oil as recited in claim 1. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants further argue that there is no suggestion or motivation for one skilled in the art to combine the selected references. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce

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the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Deckers et al. (US 6,146,645) teach a composition which comprises soybean oil and/or cucurbita (marrow) oil, wherein the oil is obtained from seeds of the plant, which is useful for combating hair loss. Duranton et al. teach a composition which contains borage oil and has hair growth-modulating properties (i.e. it is intended to promote the growth of hair). Francis beneficially teaches a mixture (composition) which contains nettle and is used for restoring hair growth. Segelman teaches a composition for preventing and treating hair loss which is made from soybeans in powdered form and contains isoflavones. Therefore, the skilled artisan would have been motivated to combine the components instantly claimed, as each was known in the art at the time the instant application was filed to be useful for the same purpose (re-growth of hair).

Applicants have also argued that even if the claimed invention is obvious in view of the instantly cited references, that the obviousness is rebutted in view of the unexpected advantageous properties supported by the comparative test provided. This is not persuasive, however, as the evidence provided demonstrates results which would be expected, as each of the components present in the instantly claimed composition were known in the art at the time the claimed invention was made to be useful for the re-growth of hair. Thus, it would have been obvious to advantageously combine all of

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the components in order to achieve the result of a greater amount of hair re-growth than would be achieved by the use of the components separately.

The rejection is deemed proper and is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick
Examiner
Art Unit 1655



CHRISTOPHER R. TATE
PRIMARY EXAMINER